



Drug Enforcement Administration

[Docket No. DEA-826]

Bulk Manufacturer of Controlled Substances Application: Patheon API

Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Manufacturing, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Such persons may also file a written request for a hearing on the application on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 18, 2021, Patheon API Manufacturing, Inc., 309 Delaware Street Greenville, South Carolina 29605-5420, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I

5-Methoxy-N-N-Dimethyltryptamine	7431	I
a-Methyltryptamine	7432	I
Psilocybin	7437	I
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

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